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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

LAM, A

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

07/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/334,858	MANN ET AL.
	Examiner Ann Y. Lam	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 April 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-70 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-70 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____.

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumura, 5,050,612.

Matsumura discloses a glucose sensor and insulin reservoir/pump on the body, and a microprocessor that communicates with the sensor and the pump via wireless means, see column 16, lines 32-40. In one embodiment, the glucose sensor is in a remote location transmitting data to the microprocessor in the wrists device and the insulin pump is also located remotely receiving transmitted instructions from the same microprocessor, see column 16, lines 44-47. Thus, Matsumura discloses a housing, which includes the pump, see column 16, line 46. It is inherent that the pump has a processor, and it is also inherent that there is a receiver coupled to the housing for receiving remotely generated commands, since the pump receives transmitted instructions from a microprocessor, see column 16, line 46-47. The infusion device is also capable of being concealed from view on an individual, see column 16, lines 33-34.

Moreover, Matsumura discloses that a microprocessor triggers the pump to infuse insulin at a pre-programmed rate, see column 13, lines 26-27. Matsumura also discloses that a computer program can be provided so that insulin is not continued to be pumped out when the blood glucose level has become low in response to insulin

pumped out earlier, see column 14, lines 24-26. It is inherent that there is an indicator to indicate to the user that a computer program is running. Thus, it is inherent that there is an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device, since applying a program

As to claims 2, Matsumura discloses a memory for storing programs, see column 13, line 27. The receiver is also capable of receiving software updates and facilitating remote programming of external infusion device capabilities, see column 13, line 27, and column 16, lines 44-47.

As to claim 3, the external infusion device includes a memory that is capable of storing a patient infusion history and pump activity, see column 13, lines 26-27.

As to claim 4, the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 35-36

As to claim 5, the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 6, the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion

device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 7, the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 8, the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 9, the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device, see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 10, the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device see column 13, lines 26-32, and lines 45-48, and column 14, lines 24-27, and column 16, lines 33-47.

As to claim 11, Matsumura discloses that a microprocessor in a wrist device is located remotely from an insulin pump and the insulin pump remotely receives transmitted instructions from the microprocessor, see column 16, lines 44-47. The microprocessor is part of the remote commander, as claimed by Applicant. It is inherent that the Matsumura device includes a commander housing, and a keypad coupled to

the commander housing for inputting commands. Matsumura also discloses that the insulin reservoir/pump can be located on the body, and a microprocessor can communicate with the pump via wireless means, see column 16, lines 33-40. It is inherent that there is a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device. Thus, Matsumura discloses a remote commander including a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device.

As to claim 12, Matsumura discloses a transmitter that is capable of verifying receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device, see column 16, lines 46-47.

As to claim 13, the remote commander is sized to fit on a key ring, see column 16, line 45. The remote commander includes the microprocessor as disclosed by Matsumura.

2. Claims 1-12, 20-43, 52-55, 58-64 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by DeCant, Jr. et al., 4,443,218. DeCant discloses a pump for delivery of insulin, wherein the pump has the ability to deliver infuse at a wide range of bolus and basal flow rate, and allow programming

allow a patient to set meal characteristics so that the bolus dose can be tailored for each meal, see column 2, lines 21-42. More specifically, DeCant discloses that the device permits the patient to change the bolus rate according to certain requirements, for example, to match his caloric intake during each meal, see column 5, lines 56-59. DeCant discloses that a microprocessor controls the basal and bolus rates of infusate flow, see column 8, lines 47-48. DeCant moreover discloses that the bolus flow is selected based upon the estimated glucose intake, see column 9, lines 11-13. DeCant also discloses that means are provided for reprogramming the microprocessor to change the infusate flow schedule after the apparatus is implanted in the body without having to invade the body. In one embodiment, such means include a telemetry transceiver (92) having an antenna (95) inside housing (12). DeCant teaches that telemetry signals from a programmer and transmitter located outside the patient's body are picked up by antenna (94) and conditioned in the transceiver (92) which thereupon emits appropriate signals to the microprocessor to effect the program change, see column 8, lines 53-63.

Thus, DeCant discloses a housing (12), a receiver coupled to the housing for receiving remotely generated commands, see lines 53-63, a processor coupled to the housing and receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands, see lines 53-63. Since there is a means provided for reprogramming the microprocessor to change the infusate flow schedule, see column 53-63, it is inherent that there is an indication device to

indicate when a command has been received and to indicate when the command is being utilized to control the external infusion device.

As to claims 2, DeCant discloses a memory for storing programs, and the receiver is also capable of receiving software updates and facilitating remote programming of external infusion device capabilities, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 3, the external infusion device includes a memory that is capable of storing a patient infusion history and pump activity, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 4, the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 5, the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 6, the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 7, the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 8, the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 9, the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 10, the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 11, DeCant discloses a remote commander including a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device, see column 8, lines 53-63, and column 13, lines 3-11.

As to claim 12, DeCant discloses a transmitter that is capable of verifying receipt of commands from the remote commander, wherein the remote commander further

includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device, see , see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 20, the remote commander is capable of providing remote commands at a distance greater than 1 inch, see column 8, lines 53-63.

As to claim 21, the processor of the external infusion device has a unique identification code, and the remote commander includes the capability to read and learn the unique identification code of the external infusion device, and the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices.

As to claim 22, the remote commander is considered to have a unique identification code, and the processor of the external infusion device inherently includes the capability to read and learn the unique identification code of the remote commander, and the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other remote commanders.

As to claim 23, the remote commander includes a mode that permits physician controlled programming of specific capabilities of the external infusion device to the exclusion of the user, see column 9, lines 11-17.

As to claim 24, the remote commander may also includes a link to a computer to allow computer programming to initiate or alter available capabilities of the external

infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 25, the external infusion device includes a memory for storing programs, column 13, lines 26-32, and the receiver is capable of receiving software updates to facilitate remote programming of external infusion device capabilities, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 26, the remote commander is capable of receiving data from another medical device and relaying the received data to the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 27, the remote commander is capable of remotely commanding and controlling the other medical device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 28, the remote commander is capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48.

As to claim 29, the remote commander is capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48.

As to claim 30, the remote commander is capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48.

As to claim 31, the remote commander is capable of programming and suspending delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 32, the remote commander is capable of programming and activating an extended bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 33, the remote commander is capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 34, the remote commander is capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 35, DeCant discloses a bolus estimator used in conjunction with a processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63. Also, it is inherent

that there is an indication device to indicate when an amount of fluid to be infused has been calculated, since the DeCant device allows the patient to change the bolus rate to match his caloric intake during a meal.

As to claim 36, the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 37, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claims 38 and 39, the liquid to be infused is insulin, and the material to be ingested is carbohydrates, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 40, the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator, see column 9, lines 11-17. The program allowing only the physician's programmer is considered to be the lockout to prevent the calculation of a bolus.

As to claim 41, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 42, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 43, it is inherent that there is a duration factor to determine a valued of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of fluid to be infused, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claims 52 and 53, it is inherent that the keypad is capable of selecting one of at least two personal delivery patterns, and that there is an indication device that is capable of indicating the selected personal delivery a pattern, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 54, there is an indication device to indicate the basal rate profiles, see column 2, lines 20-23, and column 8, lines 47-48.

As to claim 55, there is in indication device that is capable of indicating the selected bolus type, see column 2, lines 20-23, and column 8, lines 47-48.

As to claim 58, the remote commander is considered to be portable.

As to claim 59, the transmitter wirelessly transmits commands to the receiver.

As to claims 60 and 61, remote commander is considered to have a unique identification code, and the processor is capable of storing the unique identification code.

As to claim 62, the remote commander establish non-line of sight communication with the external infusion device see column 8, 53-63, column 13, lines 3-11.

As to claim 63, the receiver is considered to include a standby mode, wherein the receiver does not receive, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 64, the receiver is considered to periodically become active, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 70, at least two personal delivery patterns are programmable by a user, see column 2, lines 21-42.

Claim Rejections - 35 USC § 103

Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218, in view of Bentsen et al, 6,009,339.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose the remote commander as using radio frequency or optical frequency to transmit remote commands to the external infusion device.

Bentsen discloses a telemetric communication device providing radio frequency or optical frequency signals, see column 30, lines 63-65. It would have been obvious to use radio frequency or optical frequency signals as taught by Bentsen, as the telemetry signal in the DeCant device.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218, in view of Dempsey et al., 5,687,734.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose the remote commander as using infrared frequency to transmit remote commands to the external infusion device.

Dempsey discloses infrared frequency as a telemetry signal, see column 6, lines 50-60. It would have been obvious to use an infrared frequency, as taught by Dempsey, as the telemetry signal in the DeCant device.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218, in view of Feierbach, 5,861,018.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose the remote commander as using ultrasonic frequencies or audio frequencies to transmit remote commands to the external infusion device.

Feierbach discloses use of ultrasound frequency signal as part of a transdermal communication system, see column 5, line 18. It would have been obvious to use ultrasound frequencies in the DeCant device to provide communication between the remote commander and the external infusion device. The ultrasound frequency is also considered to be an audio frequency, as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218, in view of Batina et al., 4, 550,731.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose the remote commander as using magnetic effects to transmit remote commands to the external infusion device.

Batina discloses magnetic frequencies as a telemetric communication device, see column 3, lines 5-11. It would have been obvious to use magnetic frequencies, as taught by Batina, as the telemetry signal in the DeCant device.

Claims 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218, in view of Dent, 5,609,060.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose a vibration alarm capable of assisting in removing gas bubbles from the fluid in the reservoir during priming of the external infusion device. Nor does DeCant disclose the indication device as producing an audible indication, or a vibratory indication.

However, it would have been obvious to provide an indication that produces an audible or vibratory indication, as an alternative to, for example, a visual indication.

Also, Dent discloses a priming operation wherein vibration is applied to the blood channel as the pump is driven at a constant speed, thereby removing bubble from the inner wall of the channel, see column 2, lines 8-14. It is implied that there is a vibration device.

It would have been obvious to provide a vibration device to remove bubble, as taught by Dent, on the DeCant pump, as would be desirable before using the medical pump on a patient.

Claims 51, 56, 57, 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCant, Jr. et al., 4,443,218.

DeCant discloses the invention substantially as claimed, see above. However, DeCant does not disclose the indication device as producing an audible indication, or a vibratory indication. However, it would have been obvious to provide an indication that produces an audible or vibratory indication, as an alternative to, for example, a visual indication.

As to claim 51, it would have been obvious to provide an indication device to indicate the estimate of remaining battery power.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
June 30, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER

7/2/01